



Maryland
Department of
the Environment

Larry Hogan, Governor
Boyd Rutherford, Lt. Governor

Ben Grumbles, Secretary
Horacio Tablada, Deputy Secretary

FEB 28 2020

Mr. Andrew Bauer
Trinity Sterile, Inc.
201 Kiley Dr.
Salisbury, MD 21801

Dear Mr. Bauer:

Enclosed please find your State Permit to Operate for the Trinity Sterile, Inc. facility located in Salisbury, MD. The permit will expire on February 28, 2025. The permit contains both general conditions, which apply to all permit-to-operate holders in Maryland, and specific conditions, which apply to your facility's particular operations.

Please be reminded that an emissions based fee must be paid annually and is due by the anniversary date of the permit. The Department will bill you prior to the anniversary date for the annual fee.

Please be aware that the EPA is considering new regulations with regards to ethylene oxide emissions. Changes made to the National Emissions Standards for Hazardous Air Pollutants under 40 CFR 63, Subpart O for Ethylene Oxide Emissions Standards for Sterilization Facilities may affect your facility.

If you have any questions regarding the issuance of this permit or the annual fee, please contact Sarah Wells at (410) 537-3254.

Sincerely,

A handwritten signature in black ink, reading "Suna Yi Sariseak".

Suna Yi Sariseak, Manager
Air Quality Permits Program
Air & Radiation Administration

SYS/jm

Enclosure

KEEP PERMIT AT SITE

CONTROL NO. B- 05466

Larry Hogan
Governor



Ben Grumbles
Secretary

DEPARTMENT OF THE ENVIRONMENT

Air and Radiation Administration
1800 Washington Boulevard, Suite 720
Baltimore, MD 21230

☐ Construction Permit

☒ Operating Permit

PERMIT NO. 045-0139

DATE ISSUED March 1, 2020

PERMIT FEE To be paid in accordance with
COMAR 26.11.02.19B

EXPIRATION DATE February 28, 2025

LEGAL OWNER & ADDRESS

Trinity Sterile, Inc.
201 Kiley Drive
Salisbury, Maryland 21801
Attn: Mr. Andrew Bauer

SITE

Trinity Sterile, Inc.
201 Kiley Drive
Salisbury, MD 21801
AI #1506

SOURCE DESCRIPTION

One (1) medical device ethylene oxide (ETO) sterilization facility.

This source is subject to the conditions described on the attached pages.

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Program Manager

Director, Air and Radiation Administration

TRINITY STERILE, INC.
PERMIT-TO-OPERATE
PERMIT No. 045-0139

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This permit-to-operate incorporates requirements for the following registered installations:

ARA Registration Number	Description	Date of Installation
045-0139-7-0023	One (1) medical device ethylene oxide (ETO) sterilization process consisting of one (1) ETO sterilization chamber and two (2) aeration rooms controlled by one (1) acid wet scrubber.	1991 and modified in 2009

Part A – General Provisions

- (1) The application (Form 26) received on November 27, 2019 at the Maryland Department of the Environment ("Department") for the renewal of the Permittee's permit-to-operate is incorporated into this permit by reference. If there are any conflicts between representations in the application and representations in this permit, the representations in the permit shall govern. Estimates of dimensions, volumes, emissions rates, operating rates, feed rates and hours of operation included in the application for renewal do not constitute enforceable numeric limits beyond the extent necessary for compliance with applicable requirements.
- (2) Upon presentation of credentials, representatives of the Maryland Department of the Environment and the Wicomico County Health Department shall at any reasonable time be granted, without delay and without prior notification, access to the Permittee's property and permitted to:
 - (a) determine compliance with the requirements of this permit and any applicable regulations;
 - (b) sample, as necessary to determine compliance with requirements of this permit and applicable regulations, any materials stored or processed on site, any waste materials, and any discharge into the environment;

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- (c) inspect any monitoring equipment required by applicable regulations or by any permit issued by the Department's Air and Radiation Administration;
 - (d) review and copy any records, including all documents required to be maintained by this permit and by applicable regulations, relevant to the Department's determination of compliance with an air pollution control requirement; and
 - (e) obtain any photographic documentation or evidence necessary to determine compliance with the requirements of this permit and applicable regulations.
- (3) If any provision of this permit is declared by proper authority to be invalid, the remaining provisions of the permit shall remain in effect.
- (4) Nothing in this permit authorizes the violation of any rule or regulation or the creation of a nuisance or air pollution.

Part B – Applicable Regulations

- (1) This source is subject to all applicable federal air pollution control requirements including, but not limited to, the following regulations:

All applicable terms, provisions, emissions standards, testing, monitoring, record keeping, and reporting requirements included in the National Emissions Standards for Hazardous Air Pollutants (NESHAP) promulgated under 40 CFR 63, Subparts A and O for Ethylene Oxide Emissions Standards for Sterilization Facilities.

All notifications required under 40 CFR 63, Subparts A and O shall be submitted to both of the following:

The Administrator
Compliance Program
Maryland Department of the Environment
Air and Radiation Administration
1800 Washington Boulevard, STE 715
Baltimore MD 21230

and

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Director, Air Protection Division
U.S. EPA – Region 3
Mail Code 3AP00
1650 Arch Street
Philadelphia, PA 19103-2029

- (2) This source is subject to all applicable federally enforceable State air pollution control requirements including, but not limited to, the following regulations:
- (a) COMAR 26.11.01.07C, which requires that the Permittee report to the Department occurrences of excess emissions.
 - (b) COMAR 26.11.02.09A, which requires that the Permittee obtain a permit-to-construct if an installation is to be modified in a manner that would cause a change in the quantity, nature, or characteristics of emissions referenced in the permit-to-construct issued for that installation.
 - (c) COMAR 26.11.06.02C(1), which limits visible emissions other than uncombined water to not more than 20 percent opacity.
 - (d) COMAR 26.11.06.03B(1), which limits the concentration of particulate matter in any exhaust gases to not more than 0.05 grains per standard cubic foot of dry exhaust gas.
- (3) This source is subject to all applicable State-only enforceable air pollution control requirements including, but not limited to, the following regulations:
- (a) COMAR 26.11.02.13A(61), which requires that the Permittee maintain and renew as required a valid State permit-to-operate issued by the Department.
 - (b) COMAR 26.11.02.14D, which requires that the Permittee submit to the Department not later than 60 days prior to expiration of this permit a completed application for renewal.
 - (c) COMAR 26.11.02.19C & D, which require that the Permittee submit to the Department annual certifications of emissions, and that the Permittee maintain sufficient records to support the emissions information presented in such submittals.
 - (d) COMAR 26.11.06.08 and 26.11.06.09, which generally prohibit the discharge of emissions beyond the property line in such a manner that a nuisance or air pollution is created.

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- (e) COMAR 26.11.15.05, which requires that the Permittee implement "Best Available Control Technology for Toxics" (T – BACT) to control emissions of toxic air pollutants.
- (f) COMAR 26.11.15.06, which prohibits the discharge of toxic air pollutants to the extent that such emissions would unreasonably endanger human health.

Part C – Operating Conditions

- (1) The Permittee shall maintain and operate all installations and associated air pollution control equipment so as to assure full and continuous compliance with all applicable air pollution control regulations and permit conditions.
- (2) The Permittee shall properly maintain, calibrate, and operate all control panel instrumentation and all devices employed to monitor performance of the facility's air pollution control devices.
- (3) The Permittee shall comply with the standards of 40 CFR, Part 63, Subpart A according to Table 1 of Section 63.360 – General Provisions Applicability to Subpart O. **[Authority: 40 CFR §63.360(a)]**
- (4) Unless the Permittee can demonstrate, to the satisfaction of the Department, that compliance with the Maryland air toxics requirements of COMAR 26.11.15.06 and the requirements of 40 CFR, Part 63, Subpart O can be achieved under alternate operating procedures, the Permittee shall operate the ETO sterilization process as follows:
 - (a) Total ethylene oxide usage for the one (1) sterilization chamber shall not exceed 60 pounds per batch.
 - (b) The ETO sterilization process shall be operated such that the exhaust gases generated from the one (1) ETO sterilization chamber and each of the two (2) aeration rooms vent through the wet acid scrubber prior to discharging to the atmosphere, unless the Permittee can demonstrate, to the satisfaction of the Department, compliance with the Maryland air toxics requirements of COMAR 26.11.15.06 and the requirements of 40 CFR, Part 63, Subpart O under alternate operating procedures.
 - (c) The automated damper/valve in the manifold system shall be operated such that the gases from the one (1) sterilization chamber and the two (2) aeration rooms are prevented from simultaneously venting to the wet acid scrubber.

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- (5) In addition to the requirements of COMAR 26.11.15.06, when the one (1) ETO sterilization chamber or the two (2) aeration rooms of the ETO sterilization process are operated, the wet acid scrubber shall be operated to achieve compliance with the sterilization chamber vent emission limitations of 40 CFR §63.362(c) and the aeration room vent emission limitations of 40 CFR §63.362(d) unless the Permittee can demonstrate to the satisfaction of the Department, that compliance with the requirements can be achieved at other operating conditions. The sterilization chamber vent and the aeration room vent emission limitations do not apply during periods of malfunction. **[Authority: 40 CFR §63.360(g)(1), §63.360(g)(4), and §63.362(a) though (d)]**
- (6) In order to maintain scrubber performance, the Permittee shall continuously comply with one of the following operating limitations for the wet acid scrubber system except during periods of startup, shutdown, and malfunction: **[Authority: 40 CFR §63.363(f)]**
 - (a) The maximum ethylene glycol concentration of the scrubber liquor in the scrubbing liquor tank established during the most recent stack emissions test approved by the Department by using the procedures described in § 63.365(e)(1); or
 - (b) The maximum liquor tank level established during the most recent stack emissions test approved by the Department by using the procedures described in § 63.365(e)(2).
- (7) Any improper draining of saturated scrubber liquor (scrubber liquor that contains the maximum concentration of ethylene glycol) to remain below the maximum level shall be prohibited.

Part D – Monitoring, Record Keeping and Reporting

- (1) The Permittee shall comply with the monitoring requirements of 40 CFR §63.8 of 40 CFR, Part 63, Subpart A according to the applicability in Table 1 of 40 CFR §63.360. **[Authority: 40 CFR §63.364(a)(1)]**
- (2) For the wet acid scrubber system the Permittee shall either:
 - (a) Sample the scrubber liquor from the scrubbing liquor tank and analyze and record at least once per week, the ethylene glycol concentration of the scrubber liquor using the test methods and procedures in 40 CFR §63.365(e)(1); or

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- (b) Measure and record once per week the level of the scrubber liquor in the scrubbing liquor tank. When the scrubber liquor level in the scrubbing liquor tank reaches the maximum level determined for each tank, the Permittee shall sample the scrubber liquor and analyze and record the ethylene glycol concentration in the scrubber liquor when it is drained and removed for disposal. **[Authority: 40 CFR §63.364(a)(2), and §63.364(b)(1) and (2)]**
- (3) The concentration of the ethylene glycol in the scrubber solution and the specific gravity of the scrubber solution for the wet acid scrubber system shall be measured and recorded each time the scrubber solution of the scrubber system is replaced.
- (4) The Permittee shall maintain for at least five (5) years, and shall make available to the Department upon request, records of the following information:
 - (a) Records of the weekly logs of the specific gravity and the ethylene glycol concentration in the scrubber solutions of the wet acid scrubber system or the weekly tank level analysis for the scrubber tank of the scrubber system including the date of the analysis and the results.
 - (b) Records of the date, specific gravity, and ethylene glycol concentration in the scrubber solution when the scrubber solution of each scrubber tank of the scrubber system is replaced.
 - (c) Monthly records of ETO usage in each batch in pounds per batch for the ETO sterilization chamber.
 - (d) The Permittee shall comply with the record keeping requirements in 40 CFR §63.10(b) of Subpart A for the ETO sterilization process, according to the applicability in Table 1 of 40 CFR §63.360. **[Authority: 40 CFR §63.367(a)]** The requirements of 40 CFR §63.10(b) of Subpart A require the Permittee to maintain on site records including, but not limited to, the following:
 - (i) The occurrence and duration of each malfunction of the required air pollution control and monitoring equipment.
 - (ii) The occurrence and duration of each startup and shutdown when the startup or shutdown causes the source to exceed any applicable emission limitation.
 - (iii) All required measurements needed to demonstrate compliance with a relevant standard (including, but not

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limited to, raw performance testing measurements and raw performance evaluation measurements).

- (iv) All required maintenance performed on the air pollution control and monitoring equipment.
- (v) All results of performance tests and all measurements that may be necessary to determine the conditions of performance tests and performance evaluations.
- (vi) All documentation supporting initial notifications and notifications of compliance status under 40 CFR §63.9.

[Authority: 40 CFR §63.10(b)]

- (5) The Permittee shall submit to the Department and Region III of the U.S. Environmental Protection Agency (EPA), an ongoing compliance status report for each six (6) month period beginning January 1 and July 1 of each year as required by 40 CFR §63.10(a), (d), (e), and (f), and §63.366(a) and (c). The Permittee shall submit the reports within 30 days after the end of each six (6) month period. **[Authority: 40 CFR §63.366(a) and §63.366(a)(3)]**
- (6) The Permittee shall comply with the requirements of 40 CFR §63.366(a)(3) for the content and submittal dates for deviations and monitoring system performance reports. **[Authority: 40 CFR §63.366(a)(3)]**
- (7) Reports required by 40 CFR, Part 63, Subpart A and 40 CFR §63.366 may be sent by U.S. mail, fax, or by another courier. Submittals sent by U.S. mail shall be postmarked on or before the specified date. Submittals sent by other methods shall be received by the Department and Region III of the U.S. EPA on or before the specified date. If acceptable to both the Department and Region III of the U.S. EPA and the Permittee, reports may be submitted on electronic media. **[Authority: 40 CFR §63.366(a)(1) and (2)]**
- (8) The Permittee shall maintain at the facility for at least five (5) years records necessary to support annual certifications of emissions and demonstrations of compliance for toxic air pollutants. Such records shall include, if applicable, the following:
 - (a) mass emissions rates for each regulated pollutant, and the total mass emissions rate for all regulated pollutants for each registered source of emissions;
 - (b) accounts of the methods and assumptions used to quantify emissions;

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- (c) all operating data, including operating schedules and production data, that were used in determinations of emissions;
 - (d) amounts, types, and analyses of all fuels used;
 - (e) any records, the maintenance of which is required by this permit or by State or federal regulations, that pertain to the operation and maintenance of continuous emissions monitors, including:
 - (i) all emissions data generated by such monitors;
 - (ii) all monitor calibration data;
 - (iii) information regarding the percentage of time each monitor was available for proper service; and
 - (iv) information concerning any equipment malfunctions.
 - (f) information concerning operation, maintenance, and performance of air pollution control equipment and compliance monitoring equipment, including:
 - (i) identifications and descriptions of all such equipment;
 - (ii) operating schedules for each item of such equipment;
 - (iii) accounts of any significant maintenance performed;
 - (iv) accounts of all malfunctions and outages; and
 - (v) accounts of any episodes of reduced efficiency.
 - (g) limitations on source operation or any work practice standards that significantly affect emissions; and
 - (h) other relevant information as required by the Department.
- (9) The Permittee shall submit to the Department by April 1 of each year during the term of this permit a certification of emissions for the previous calendar year. The certifications shall be prepared in accordance with requirements, as applicable, adopted under COMAR 26.11.01.05 – 1 and COMAR 26.11.02.19D.
- (a) Certifications of emissions shall be submitted on forms obtained from the Department.

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- (b) A certification of emissions shall include mass emissions rates for each regulated pollutant, and the total mass emissions rate for all regulated pollutants for each of the Permittee's registered sources of emissions.
- (c) The person responsible for a certification of emissions shall certify the submittal to the Department in the following manner:

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

- (10) The Permittee shall submit to the Department, by April 1 of each year during the term of this permit, a written certification of the results of an analysis of emissions of toxic air pollutants from the Permittee's facility during the previous calendar year. Such analysis shall include either:
 - (a) a statement that previously submitted compliance demonstrations for emissions of toxic air pollutants remain valid; or
 - (b) a revised compliance demonstration, developed in accordance with requirements included under COMAR 26.11.15 & 16, that accounts for changes in operations, analytical methods, emissions determinations, or other factors that have invalidated previous demonstrations.
- (11) The Permittee shall report, in accordance with requirements under COMAR 26.11.01.07, occurrences of excess emissions to the Compliance Program of the Air and Radiation Administration.